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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/864,585	05/24/2001	Stanley R. Mandel	032781-003	2107

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EXAMINER
VANATTA, AMY B

ART UNIT	PAPER NUMBER
3765	

DATE MAILED: 05/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/864,585	MANDEL ET AL.	
	Examiner	Art Unit	
	Amy B. Vanatta	3765	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 March 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) *5-11,16 and 19-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,12-15,17,18 and 27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 May 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 102 and 35 USC § 103

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1, 2, 12, 15 and 18 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kuehn et al (US 6,165,183).

Kuehn et al disclose a medical device which is made of a polymer (col. 12, line 16) and is coated with an antimicrobial coating (col. 12, lines 20-21). Kuehn teaches

that the antimicrobial coating comprises "silver metal or silver compound", which includes silver ions as claimed. Kuehn also discloses the steps of coating as recited in claims 12, 15, and 18 (col. 12, lines 14-26). Kuehn discloses various medical devices which may be made of such coated material, including a clamping ring (600 or 630) as shown in Figs. 33-34 and a gripper (412) as shown in Fig. 18A. Such devices have a structure which forms a "clip" to the extent claimed. The recitation of the use of the clip for ligating or other purposes merely amounts to the intended use of the device, since the claim does not define any further structure which defines the claimed clip over the ring or gripper of Kuehn. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

Alternatively, assuming *arguendo* that the claimed ligating clip inherently has a structure which defines over the medical devices of Kuehn et al, one having routine skill in the art would recognize that the antimicrobial coated material disclosed by Kuehn would be advantageous in a ligating clip to the same extent that it is advantageous in the medical devices disclosed in the patent of Kuehn. Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make a ligating clip out of the antimicrobial coated material of Kuehn et al in order to prevent or resist infection in the patient.

4. Claims 1-4, 12-15, 17, 18, and 27 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Fox, Jr. et al (US 5,019,096).

Fox et al disclose medical devices made of polymeric material (col. 3, lines 6-24) and having surfaces coated with an antimicrobial or antibiotic coating composition. Fox discloses a method for inhibiting growth of or killing microorganisms comprising coating the medical device with an antimicrobial or antibiotic coating composition as in claim 12. Fox teaches that the antimicrobial coating may comprise silver ions, and specifically discloses the use of various silver compounds as recited in claims 3 and 13 (col. 13, lines 36-45). Fox also discloses the use of quinolones, oxacillin, or cephalosporins in the antibiotic coating (col. 13, lines 47-51), as recited in claims 4 and 14. Fox discloses the use of a biodegradable polymer material, thus being absorbable as in claims 17 and 27. The coating disclosed by Fox functions to kill microorganisms in the manner recited in claim 18. Fox teaches that a device made of this coated material is a wound clip (col. 3, line 15). Such a clip meets the structure of the claimed clip. The recitation of the use of the clip for ligating, thus being a "ligating clip", merely amounts to the intended use of the device, since the claims do not define any further structure which defines the claimed clip over the clip disclosed by Fox. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

Alternatively, assuming *arguendo* that the claimed "ligating clip" inherently has a structure which defines over the wound clip of Fox, it is noted that Fox teaches that medical devices which may be so coated are "those for use both externally and internally" and includes catheters, tubes, implants, wound clips, sutures, and grafts. Since ligating clips are a type of wound clip and fall into the grouping of medical devices which are for use internally, one having routine skill in the art would recognize that the coated material and method of Fox would be advantageous for use in the ligating clip in order to prevent or resist infection. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make a ligating clip out of the antimicrobial or antibiotic coated material of Fox in order to prevent or resist infection in the patient.

Response to Arguments

5. Applicant's arguments filed 3/6/03 have been fully considered but they are not persuasive.

With regard to Kuehn et al (6,165,183), specifically the 102(e) rejection, applicant argues that the device of Kuehn et al functions as a connector mechanism rather than as a ligation device and that the purpose and context of use of the device in Kuehn differs from that of the present invention. The Examiner contends that the use and purpose of the Kuehn device is irrelevant since the claimed structure and the claimed manipulative method steps are disclosed by Kuehn. The recitation of the use of the clip for ligating merely amounts to the intended use of the device, since the claim does not

define any further structure which defines the claimed clip over the ring or gripper of Kuehn. The fact that the device of Kuehn is used for a different purpose is irrelevant since it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

Applicant also argues that the device of Kuehn would not have made the claimed invention obvious since the ligating clip and methods defined by the rejected claims are for use in the body for ligation, and the requirements of a ligating clip differ from the devices described in Kuehn et al. The Examiner contends, however, that one having ordinary skill in the art would recognize from the teachings of Kuehn et al that coating a polymeric surgical device with an antimicrobial or antibiotic coating results in advantages which would be beneficial for ligating clips.

With regard to the Fox et al (5,019,096) rejection under 102(b), applicant argues that Fox does not describe a ligating clip and thus does not disclose every feature of the claimed invention. However, as set forth in the rejection above, the claims do not recite any structure which defines the claimed clip over the clip disclosed by Fox, and the recitation of the use of the clip for ligating, thus being a "ligating clip", merely amounts to the intended use of the device. As stated above, it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

Applicant also argues that the disclosure of Fox would not have made the claimed invention obvious in view of the differing structures and usages of the medical devices as described by Fox et al and the structure and use of ligating clips. Fox does teach, however, that medical devices which may be coated with an antimicrobial or antibiotic composition includes those for use internally. Since ligating clips are medical devices which are used internally, one having ordinary skill in the art would recognize from the teachings of Fox et al that coating a ligating clip with an antimicrobial or antibiotic coating results in advantages which would be beneficial to the same extent as disclosed by Fox et al.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy B. Vanatta whose telephone number is (703) 308-2939. The examiner can normally be reached on Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Calvert can be reached on (703) 305-1025. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3579 for regular communications and (703) 305-3579 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0861.

Amy B. Vanatta
Primary Examiner
Art Unit 3765

abv
May 8, 2003